This listing of claims will replace all prior versions and listings of claims in this application:

a.) Listing of Claims

1. [Canceled]

2. [Original] Use of a composition in the manufacture of a medicament for the treatment of breast or prostate cancer in a mammal, said composition comprising small molecular weight components of less than 3000 daltons, and having the following properties:
   (a) is extracted from bile of animals;
   (b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*;
   (c) is capable of modulating tumor necrosis factor production and/or release;
   (d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;
   (e) is not cytotoxic to human peripheral blood mononuclear cells; and
   (f) is not an endotoxin.

3. [Original] A pharmaceutical kit for the treatment of breast or prostate cancer in a mammal, said kit comprising:
   (1) a dosage unit of a composition and a pharmaceutically acceptable carrier wherein the composition comprises small molecular weight components of less than 3000 daltons, and has the following properties:
      (a) is extracted from bile of animals;
      (b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*;
      (c) is capable of modulating tumor necrosis factor production and/or release;
      (d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;

(e) is not cytotoxic to human peripheral blood mononuclear cells;

(f) is not an endotoxin; and

(2) a dosage unit of one or more chemotherapeutic drug(s) and a pharmaceutically acceptable carrier,

said (1) and (2) being provided in amounts that that are effective in combination for killing tumour or metastatic cells.

4. [Original] The kit according to claim 3, wherein said one or more chemotherapeutic drug(s) is gemcitabine, 5-fluorouracil, dacarbazine, taxol, taxotere, cisplatin or mitoxantrone.

5. [Original] A pharmaceutical composition for the treatment of breast or prostate cancer in a mammal, said pharmaceutical composition comprising:

(1) a composition comprising small molecular weight components of less than 3000 daltons, and having the following properties:

(a) is extracted from bile of animals;

(b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*;

(c) is capable of modulating tumor necrosis factor production and/or release;

(d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;

(e) is not cytotoxic to human peripheral blood mononuclear cells;

(f) is not an endotoxin;

(2) one or more chemotherapeutic drug(s); and

(3) a pharmaceutically acceptable carrier;

wherein said pharmaceutical composition has therapeutic synergy or improves the therapeutic index in the treatment of cancer over the composition or the chemotherapeutic drug(s) alone.

6. [Previously Amended] The pharmaceutical composition according to claim 5, wherein at least one of said one or more chemotherapeutic drug(s) is gemcitabine, 5-fluorouracil, dacarbazine, taxol, taxotere, cisplatin or mitoxantrone.

7. [Previously Amended] The pharmaceutical composition according to claim 5, formulated into a sterile solution, a lyophilate, a pill, a tablet, a cream, a capsule, a suppository, a gelatin capsule, a soft gelatin capsule, a gel, a membrane or a tubelet.

8-12. [Canceled]

13. [Original] The pharmaceutical composition according to claim 5, wherein said cancer is breast cancer and said anticancer agent is taxol.

14. [Previously Amended] The pharmaceutical composition according to claim 5, wherein said pharmaceutical composition is suitable for administration via oral, topical, rectal, parenteral, local, inhalant or intracerebral delivery.

15. [Original] The pharmaceutical composition according to claim 14, wherein said parenteral delivery is achieved via intramuscular injection.

16. [Original] Use of a combination for the manufacture of a medicament for the treatment of breast or prostate cancer in a mammal, said combination comprising:

(1) a composition comprising small molecular weight components of less than 3000 daltons, and having the following properties:

(a) is extracted from bile of animals;

(b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*;

(c) is capable of modulating tumor necrosis factor production and/or

release;

(d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;

(e) is not cytotoxic to human peripheral blood mononuclear cells;

(f) is not an endotoxin; and

(2) one or more anticancer agent(s),

wherein said combination has therapeutic synergy or improves the therapeutic index in the treatment of cancer over the composition or the anticancer agent(s) alone.

17. [Previously amended] A method for treating breast or prostate cancer in a mammal, comprising administering to said mammal a therapeutically effective amount of a composition comprising small molecular weight components of less than 3000 daltons, and having the following properties:

(a) is extracted from bile of animals;

(b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*;

(c) is capable of modulating tumor necrosis factor production and/or release;

(d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;

(e) is not cytotoxic to human peripheral blood mononuclear cells;

(f) is not an endotoxin.

18. [Currently amended] A method for treating breast or prostate cancer in a mammal, comprising administering to said mammal a therapeutically effective amount of a composition and one or more anticancer agent(s), wherein said composition comprises small molecular weight components of less than 3000 daltons, and has the following properties:

(a) is extracted from bile of animals;

(b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in*

vivo;

(c) is capable of modulating tumor necrosis factor production and/or release;

(d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;

(e) is not cytotoxic to human peripheral blood mononuclear cells; and

(f) is not an endotoxin.

19. [Original] The method according to claim 18, wherein said anticancer agent(s) is selected from the group consisting of a chemotherapeutic drug, radiation, a gene therapy and an antisense oligonucleotide.

20. [Previously amended] The method according to claim 19, wherein said anticancer agent(s) is a chemotherapeutic drug, an interleukin or an interferon.

21. [Previously amended] The method according to claim 18, wherein at least one of said one or more anticancer agent(s) is a chemotherapeutic drug.

22. [Original] The method according to claim 21, wherein the chemotherapeutic drug is gemcitabine, 5-fluorouracil, dacarbazine, taxol, taxotere, cisplatin or mitoxantrone.

23. [Previously amended] The method according to claim 17 or 18, wherein said composition or combination is formulated into a sterile solution, a lyophilate, a pill, a tablet, a cream, a capsule, a suppository, a gelatin capsule, a soft gelatin capsule, a gel, a membrane or a tubelet.

24. [Previously amended] The method according to claim 17 or 18, wherein said administering is achieved by means of oral, topical, rectal, parenteral, local, inhalant, or intracerebral delivery.

25. [Original] The method of claim 24, wherein said parenteral delivery is achieved via intramuscular injection.

26. [Previously amended] The method of claim 17 or 18, wherein peripheral blood monocytes and/or tumor associated macrophages are stimulated to express cytocidal activity in a manner that is insensitive to the inhibitory effects of prostaglandins.

27. [Previously amended] The method of claim 17 or 18, wherein suitable modulation of the immune system is elicited in said mammal by activating macrophages and/or monocytes to produce and/or release cytokines or promote activity to seek and remove or destroy cancerous cells.

28. [Currently amended] The method of claim 17 or 18, wherein the release of TNF, IL-1β and GM-CSF is stimulated in said mammal.

29. [Original] Use of a composition in the manufacture of a pharmaceutical kit for the treatment of breast or prostate cancer in a mammal, said kit comprising:

(1) a dosage unit of a composition and a pharmaceutically acceptable carrier wherein the composition comprises small molecular weight components of less than 3000 daltons, and has the following properties:

(a) is extracted from bile of animals;

(b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*;

(c) is capable of modulating tumor necrosis factor production and/or release;

(d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;

(e) is not cytotoxic to human peripheral blood mononuclear cells;

(f) is not an endotoxin; and

(2) a dosage unit of one or more chemotherapeutic drug(s) and a pharmaceutically acceptable carrier,

said (1) and (2) being provided in amounts that have therapeutic synergy or that improve the therapeutic index in the treatment of cancer over the composition or the chemotherapeutic drug(s) alone.

30. [Original] A pharmaceutical kit for the treatment of breast or prostate cancer in a mammal, said kit comprising:

(1) a dosage unit of a composition and a pharmaceutically acceptable carrier wherein the composition comprises small molecular weight components of less than 3000 daltons, and has the following properties:

(a) is extracted from bile of animals;

(b) is capable of stimulating monocytes and/or macrophages *in vitro* and/or *in vivo*;

(c) is capable of modulating tumor necrosis factor production and/or release;

(d) contains no measurable level of IL-1α, IL-1β, TNF, IL-6, IL-8, IL-4, GM-CSF or IFN-gamma;

(e) is not cytotoxic to human peripheral blood mononuclear cells;

(f) is not an endotoxin; and

(2) a dosage unit of one or more chemotherapeutic drug(s) and a pharmaceutically acceptable carrier,

said (1) and (2) being provided in amounts have therapeutic synergy or that improve the therapeutic index in the treatment of cancer over the composition or the chemotherapeutic drug(s) alone.

31. [Previously added] The method according to claim 18, wherein said composition and said one or more anticancer agent(s) are administered separately, concurrently or simultaneously.

32. [Previously added] The method according to claim 18, wherein said cancer is breast cancer and said anticancer agent is taxol.

33. [Previously added] The method according to claim 31, wherein said composition and said anticancer agent are administered concurrently.